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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,668	06/25/2003	Don Hannula	009103-020500	4758

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EXAMINER

WINAKUR, ERIC FRANK

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 01/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/606,668	Applicant(s) HANNULA ET AL.	
	Examiner Eric F Winakur	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/26; 5/10; 12/20</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Double Patenting

1. Applicant is advised that should claim 14 be found allowable, claim 16 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claim 5 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claim improperly includes a portion of a living body (forehead) as an element of the claimed invention.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1 - 7, 9 - 11, and 13 - 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Toomim et al. (USPN 5,995,857 - cited by Applicant). Toomim et al.

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teach an optical measurement arrangement for performing measurements from a subject's forehead that includes emitters and detectors attached to a substrate which may be adhesively attached to the subject or placed in contact with the subject via a cap (considered to be a type of hat) on the forehead or at any convenient position around the head. Applicant's attention is drawn to Figures 1 - 4 and the description of column 4, line 39 - column 6, line 36.

6. Claims 1 - 5, 9, 11, 12, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Cui et al. Cui et al. teach a cerebral oximetry arrangement that includes a substrate that conforms to a subject's forehead when measurements are performed and emitter and detector elements for performing the measurements. The device is adhesively attached to a subject (lateral [to the side] of the iris of at least one of the subject's eyes) and includes opaque elements to block interference from undesired light. Details of the device are provided in column 4, line 50 - column 8, line 42 and column 13, line 40 - column 14, line 18.

7. Claims 1, 2, 11, 12, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Matthews. Matthews teaches an optical measurement device that can measure oxygen saturation levels; the entire system can be incorporated into a headband (column 3, lines 18 - 21; column 4, lines 61 - 64). In use, the measurement elements are positioned lateral of (that is, to the side of) the iris of at least one of the subject's eyes (see Figure 1).

Claim Rejections - 35 USC § 103

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8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 6 - 8, 13, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matthews as applied to claims 1 and 11 above, and further in view of Sarussi et al. Matthews teaches an optical measurement device that is incorporated into a headband, but does not particularly teach that the device may be implemented in a hat. Sarussi et al. teach an optical measurement device that is similar to that of Matthews. Sarussi et al. further teach (paragraph 0034) that their device can be attached to a head covering, including a cap, a hat, or a bandana (which is similar to the headband of Matthews). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Matthews by including the optical measuring device in a hat, as taught by Sarussi et al., since Sarussi et al. teach that a hat and bandana/headband are alternate expedients for positioning the sensor on a subject's head. With regard to claim 8, the combination teaches that the sensor is attached to the head covering (see Sarussi et al., paragraph 0034) but does not teach that the unit is adhesively attached to the hat. Without a showing of unexpected results or criticality, it would have been obvious to one of ordinary skill in the art at the time of the invention to use well known elements to attach the sensor to the hat, including use of an adhesive attachment arrangement, since the combination requires such an attachment and it has

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generally been held to be within the skill level of the art to use known elements (adhesive) for their intended purpose (attaching).

10. Claims 10, 16, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matthews in view of Sarussi et al. for the reasons given in paragraphs 6 and 8 above.

Conclusion

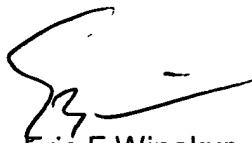
11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Applicant cites several references related to oximetry measurement. In addition, Lewis et al. (both references) and Benni teach further cerebral oximeter arrangements. Jöbsis teaches an optical measurement arrangement that can perform measurements from a subject's forehead. Alfano et al., Boas, and Odom et al. teach that physiological measurement devices can be incorporated into hats or caps.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric F Winakur whose telephone number is 571/272-4736. The examiner can normally be reached on M-Th, 7:30-5; alternate Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571/272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Eric F Winakur
Primary Examiner
Art Unit 3736

24 January 2005